

Remarks

Claims 1, 9, 10 and 11 have been amended.

The amendments to claim 1 specify L_1 and L_3 as being the outermost elastomeric layers and identify E_1 , E_2 and E_3 as being the elastomeric constants for L_1 , L_2 and L_3 , respectively. Support in the specification for these amendments may be found, for example, at page 1, Scheme 1 and lines 27-29; page 7, line 25 through page 8, Scheme II; and at page 4, lines 17-20.

The amendment to claim 9 identifies additional materials suitable for constituting the layers L_1 , L_2 and L_3 . Support for this amendment may be found, for example, at page 5, lines 4-14.

The amendment to claim 10 was made to conform to claim 9 as amended.

The amendment to claim 11 more clearly defines the claimed invention.

No new matter has been introduced by any of these amendments. After entry of the above amendments, claims 1-19 and 23-27 will be pending.

1. Rejection under 35 U.S.C. § 112, second paragraph

A. Claims 1-19 and 23-27 are rejected under 35 U.S.C. § 112, second paragraph, because the Examiner asserts that it is not clear whether the recited outer layers L_1 and L_2 of claim 1 are the outermost layers of the material.

Applicants have amended claim 1 to identify L_1 and L_3 as the outermost elastomeric layers present in the recited multilayer elastomeric material that enclose an intermediate layer L_2 . It should be clear from this recitation that the outermost elastomeric layers of the material are L_2 and either L_1 or L_3 . As described in the specification at, for example, page 7, lines 25-29, the claimed multilayer material may contain at least one non-elastomeric layer that covers L_1 or L_3 . This amendment should not be construed as a narrowing amendment because the term “outer,” when viewed in light of the specification, would have been given the same meaning. In view of this amendment to claim 1, Applicants request that the ground for this rejection be withdrawn.

B. Claims 6-8 are rejected under 35 U.S.C. § 112, second paragraph, because the Examiner asserts that the recited “E” values have no antecedent basis in claim 1.

Applicants have amended claim 1 to include the “ E_1 ,” “ E_2 ” and “ E_3 ” variables referred to

in claims 6-8 as the elastic constants corresponding to layers "L₁," "L₂" and "L₃" respectively. Similar to the amendment to claim 1 addressed in section A above, this amendment should also not be construed as a narrowing amendment given that the "E" variables simply represent a characteristic of the claimed elastomeric materials. In light of this amendment to claim 1, Applicants request that the ground for this rejection be withdrawn.

2. Rejection under 35 U.S.C. § 103(a)

A. Applicants' Statement in view of Crepeau

Claims 1-12, 14-16, 19 and 23-27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicants' alleged admission at page 1, lines 16-32 of the specification in view of U.S. Patent No. 6,391,326 to Crepeau *et al.* ("Crepeau"). Specifically, the Examiner asserts that on page 1 of the specification, Applicants have admitted that elastomeric films having L₁/L₂/L₃ structures in which intermediate layer L₂ contains an active disinfectant substance dispersed in liquid droplets and layers L₁ and L₃ are protective layers, is known. Crepeau is cited by the Examiner as teaching elastomeric films containing Applicants' polymers and plasticizers, and having chemical substances in liquid droplet form, wherein the droplets have diameters of 10 µm or more. The Examiner asserts that because the films described in Crepeau are used to make gloves, fingerstall, condoms and dressing, it would have been obvious to a skilled artisan to employ them as the intermediate layer in Applicants' claimed films. Further, the Examiner contends that the selection of films having suitable breaking stress/thickness properties is a matter of engineering choice, depending on the degree of rupturability desired in the outer film layers.

Applicants disagree with the Examiner's assessment of the statement made by Applicants regarding the nature of the prior art and the particular applicability of Crepeau to Applicants' claimed invention. While Applicants have acknowledged that the prior art does generally describe multilayered films in which an intermediate layer may contain an active chemical agent in the form of droplets, Applicants note that such films do not exhibit the particular high-performance qualities observed in Applicants' claimed elastomeric materials.

More specifically, Applicants have shown that the rupture of the constituent layers of an elastomeric multilayer material essentially depends on the resistance of the layers to a cutting or piercing force, which is proportional to the product of the breaking stress (σ) for each layer multiplied by the thickness (e) of each layer. The breaking stress of the intermediate layer further depends on the amount of the composition comprising an active agent contained in the layer.

The claimed elastomeric multilayer material must fulfill the requirements that the resistance of the intermediate layer L_2 is less than that of either of the outer layers L_1 or L_3 . These requirements are summarized by the mathematical formulae referred to by Applicants as the "double inequality" relationship: $(\sigma_2 \times e_2) < (\sigma_1 \times e_1)$ and $(\sigma_2 \times e_2) < (\sigma_3 \times e_3)$. Otherwise, the speed of the droplets of the active agent contained in L_2 is not sufficient to allow the active agent reaching a piercing or rupturing object a sufficient amount of time to inactivate potentially dangerous microorganisms on the object before the object has completely perforated the entire material and penetrated the skin.

When a multilayer material does not satisfy the above discussed double inequality relationship between its constituent layers, as shown in Applicants' comparative example 3, the volume of the active agent deposited on the piercing object after perforation is unexpectedly 10 times less than the volume deposited when using a multilayer material in which the double inequality relationship is satisfied (see *e.g.*, example 1). Further, the speed of expulsion of the active agent is unexpectedly 5 times slower in the multilayer film of comparative example 3 compared to the multilayer film of example 1.

The prior art does not teach or suggest the above-defined double inequality relationship that must exist between the layers of Applicants' claimed multilayer elastomeric material. Crepeau simply states that the described emulsions may be used with "various elastomeric materials usually used in the medical or paramedical field" (col. 1, lines 63-66). Without further information regarding the relative breaking stresses and thicknesses of the layers of these elastomeric materials, a skilled artisan would clearly not be motivated to produce Applicants' claimed invention. In fact, the absence of any technical information indicates that little or no modification of the existing elastomeric materials is contemplated by Crepeau.

The Examiner asserts that designing elastomeric materials with the specific properties claimed by Applicants (*e.g.*, the double inequality relationship between the layers) is merely an engineering choice. Applicants disagree and note that the Examiner has not cited any prior art reference that would support her assertion. Thus, the Examiner has subjectively assessed the level of one of ordinary skill in this particular art in the absence of supporting documentation.

As discussed above, Applicants have shown in a comparative example that a functioning multilayer elastomeric material can be prepared in which the structural relationships between the layers is different from the one recited in claim 1. However, at least in the stated example, this material is inferior to a material that is prepared subject to the recited inequality relationship. Although the Examiner contends that it would be a simple engineering choice to develop the inequality relationship, (*i.e.*, to transform the comparative example material to a material with superior properties), the Examiner has not indicated how a skilled artisan would know that the rupture of the constituent layers of an elastomeric multilayer material essentially depends on the resistance of the layers to a cutting or piercing force, which is proportional to the product of the breaking stress (σ) for each layer multiplied by the thickness (e) of each layer. The art cited by the Examiner does not teach or suggest any of these properties or their interrelationships.

Further, there is no indication in any of the art cited by the Examiner that once these interrelationships have been determined, that a skilled artisan would be motivated to prepare materials that are subject to Applicants' double inequality relationship, given that, as discussed above, these materials possess unexpected advantages over existing materials. These advantages, such as increased volume and rate of expulsion of the active agent, which provide a superior product, would not have been foreseen by a skilled artisan as resulting from the particular modification of the layers of existing elastomeric materials as performed and claimed by Applicants. In summary, neither Crepeau nor Applicants' statement regarding prior art elastomeric materials render obvious Applicants' claimed multilayer elastomeric material in which two outermost elastomeric barrier layers L_1 and L_2 enclose an intermediate layer L_3 and the layers satisfy the double inequality $(\sigma_{2Tot} \cdot e_2) < (\sigma_1 \cdot e_1)$ and $(\sigma_{2Tot} \cdot e_2) < (\sigma_3 \cdot e_3)$. Applicants therefore respectfully request that the ground for this rejection be withdrawn.

B. Applicants' Statement in view of Crepeau and Hoerner

Claims 13 and 17-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Applicants' alleged admission in view of Crepeau and U.S. Patent No. 6,020,070 to Hoerner *et al.* ("Hoerner"). According to the Examiner, Hoerner teaches films having active agents in gel-containing layers. The Examiner asserts that it would have been obvious to a skilled artisan to employ the gel-containing layer and multiple outer layers of Hoerner in the films suggested by the combination of Applicants' alleged admission and Crepeau in order to improve the flexibility of the intermediate layers.

Because Hoerner does not teach or suggest Applicants' recited double inequality relationship between the layers of Applicants' claimed elastomeric multilayered material, Hoerner cannot remedy the deficiencies present in Crepeau or in Applicants' alleged admission. As such, the grounds for this rejection should be withdrawn.

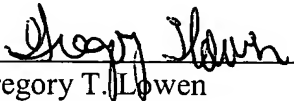
3. Conclusion

Upon consideration of the foregoing, it will be recognized that Applicants have fully and appropriately responded to all of the Examiner's rejections. Accordingly, the claims are believed to be in proper form in all respects and a favorable action on the merits is respectfully requested. The Examiner is invited to contact the undersigned with any questions or concerns that may prevent this requested allowance.

Except for issues payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Dated: **January 18, 2005**
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